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WORLD HEALTH ORGANIZATION DEVELOPMENT OF AN INTERNATIONAL CODE FOR THE MARKETING OF INFANT FORMULAS:

BACKGROUND AND PERSPECTIVE

World Health Organization Development of an International Code for The Marketing of Infant Formulas:

Background and Perspective

The World Health Organization's development of an international marketing code for breastmilk substitutes has assumed many complex and disturbing dimensions.

It is virtually impossible to discuss infant nutrition, infant formulas, breastmilk substitutes, or related issues in a proper context without first giving some attention to breast feeding. Although breast feeding has, of course, been a critically important biological function throughout history, only within the last few decades has it received its due attention.

First, it is recognized that breast feeding is clearly a time-proven and effective way of feeding young infants. There is no debate on this. Under favorable conditions, breast feeding is generally considered the ideal way of feeding babies. Breastmilk provides nutrients, i.e., protein, fat, carbohydrate, vitamins, minerals, and water of a quality and quantity naturally tailored to meet the needs of the young infant.

It is well established that breastmilk from a healthy, well-nourished mother can fully me the nutritional needs of the normal growing infant for the first 4-6 months. At about 4-6 months, nutritious and hygienically prepared supplementary foods of appropriate consistency should be added to the infant's diet to continue to meet his increasing needs. This is an important point. Simplistic ideas (or ideals) of mothers breast feeding

exclusively, i.e., with no supplementary foods, for a year or two are grossly inaccurate and seriously detract from a proper understanding of good infant nutrition. Another important point is that breastmilk from a poorly nourished or unhealthy mother may be inadequate to fully meet all the infant's increasing needs after only 2-3 months. In these cases, of course, earlier supplementation with nutritionally sound and physiologically appropriate food is necessary. [illegible]urally, every effort should also be made to overcome the mother's poor health and poor nutritional condition to help her to improve the quantity and, to some extent, the quality of her breast milk.

Generally, breast milk not only provides nutrition which is naturally tailored to meet the needs of infants, breast feeding may also provide certain emotional benefits to the mother and her infant, especially if breast feeding is desired by the mother. Importantly, breast milk also provides some immunological and other protective factors which may help protect infants from infections or disease, particularly in areas of poverty, poor sanitation, and inadequate health care. And finally, lactation is well-recognized to have important anti-ovulatory effects which can inhibit conception.

While breast feeding may offer several advantages and should be encouraged, it is important to recognize that breast feeding is not universally desired by women, nor is breast feeding an automatic or unfailing process. Among other things, successful breast feeding requires:

- A supportive cultural environment
- A supportive social network

- A suitable emotional attitude
- A reasonably healthy, well-nourished mother
- An infant with mature sucking reflexes who is also reasonably healthy, and
- Appropriate economic priorities

It is widely recognized that problems in any of these areas can interfere with successful breast feeding. Without going into detail, it is apparent that for a wide variety of complex social, emotional, medical, and other reasons, breast feeding might not be chosen or it might be unsuccessful, inappropriate, or stopped early, or it might require early supplementation.

In all of these cases, infant formulas which are scientifically designed to be nutritionally similar to breast milk are recognized as the best alternative. While strongly encouraging breast feeding, the Committee on Nutrition of the American Academy of Pediatrics has stated:*

> When breast feeding is unsuccessful, inappropriate or stopped early, infant formulas provide the best alternative for meeting nutritional needs during the first year.

Infant formulas are widely recognized as being far superior to other alternatives to breast milk which have been, and unfortunately continue to be widely used in many areas of the world. These include unmodified cow's milk, other animal milks, skim milk, sweetened condensed milk, evaporated milk, and even rice water, sugar water, thin porridges, local teas, and others, with consequences which range from moderately unsatisfactory to disastrous. These, of course, are the kinds of inappropriate foods which infant formulas are designed to displace and not breast milk.

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*"Commentary on Breast Feeding and Infant Formulas, Including Proposed Standards

A dramatic endorsement of the contribution of infant formulas was contained in a recent report* to the Food and Drug Administration in the United States. The report stated:

> The availability of satisfactory infant formulas is relatively recent. Until the 20th Century, there was virtually no safe and reliable alternative to breast feeding and few infants not suckled by mothers or wet nurses survived their first year.

The critical importance of infant formulas is well established.

The real origin of the World Health Organization's efforts to develop an international code to govern the marketing of infant formulas could be marked by a 1970 meeting of several international health professionals and representatives of a number of infant food companies in Bogota, Colombia. That meeting, sponsored by several United Nations Agencies, was one of the first to raise serious concerns about trends toward a declining duration of breastfeeding, and to a lesser extent, a reduced frequency of initiation of breastfeeding which were observed particularly in urban areas of some developing countries. With those trends, it was recognized that many of the advantages of breastfeeding were not being fully

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*"A Background Paper on Infant Formulas," Prepared for Bureau of Foods; Food and Drug Administration; Department of Health, Education and Welfare; S. A. Anderson, H. I. Chinn, K. D. Fisher, Life Sciences Research Office, Federation of American Societies for Experimental Biology; February, 1980.

realized, advantages considered of particular importance in areas of poverty, poor sanitation, lack of education, and so forth. Some of the factors which were identified as possibly influencing the declining patterns of breastfeeding included:

- The erosion of social support systems for breastfeeding women.
- Changing roles of women in society.
- Entry of women into the urban work force.
- Medical care practices and attitudes.
- Changes in maternity ward routines.
- Emotional, cultural and social trauma of rapid urbanization.
- Continuing or worsening problems of poor maternal nutrition and health.

Also, it was suggested that certain commercial influences, such as inappropriate advertising or promotion of infant foods directly to consumers could be listed among the factors. However, the internal report* of that 1970 meeting pointed out that:

> The existing evidence tends to show that the decline in breastfeeding is due to very complex sociological and economic factors. Because of this complexity, no constructive purpose would be served at this time in relating the worldwide decline in breastfeeding to any single factor, including processed infant foods.

Soon after this 1970 meeting, health professionals, international health agencies, governments, industry and others examined the complex problems and cooperatively pursued solutions. One of the most sensible statements of the problems was the one issued in 1972 by the Protein Advisory Group of the United Nations Systems.** It rationally defined

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* "Internal Report: PAHO/WHO-UNICEF Conference of Pediatricians and Representatives of the Infant Food Industry on Infant Feeding in Latin America and the Caribbean, Bogota, 5-7 November 1980. (The internal report was intended only for the use of participants and their organizations.)

**"Promotion of Special Foods (Infant Formula and Processed Protein Foods) for Vulnerable Groups," Protein Advisory Group of the United Nations

the value and the limitations of breastfeeding, the problems of poverty, maternal illness and malnutrition, inappropriate weaning practices, poor hygiene, etc., and presented several recommendations to governments, U.N. agencies, physicians, and industry. Of course, the Protein Advisory Group recommended several measures to encourage and facilitate breast-feeding. But it is noteworthy that, among other things, the Protein Advisory Group's statement also said:

> Governments should take the following steps to assist the introduction of nutritious foods for infants and young children at the lowest feasible cost:
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> - initiate specific legislative action to reduce direct and indirect fiscal burdens on processed infant formulas and weaning foods;
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> - consider subsidy programs to provide nutritious infant formulas and weaning foods to the most vulnerable and the lowest income groups. In some situations, governments should provide also for free distribution of these foods to the vulnerable groups in the lowest income families.
>
> - provide strong support in organizing and financing educational programs for promoting good nutrition among infants and young children; these may include practical training in correct product usage for all mothers, including those to whom the products are provided free or at low cost. Such programs should be carried out in close collaboration with physicians caring for mothers and children and with the industry involved...
>
> - stimulate use of mass media channels for both educational and ethical product promotion communication;
>
> - encourage recognition of promotion as an essential component of any marketing program to establish widespread consumer use of nutritious foods for children...

These and the several other recommendations of the Protein Advisory Group were well considered and reasonable. As it happened, only a year or two after the Protein Advisory Group's recommendations, certain individuals and groups chose to single out marketing practices of the infant formula industry and allege that they alone comprised one of the primary

causes of declining breast feeding in less developed countries. This simple allegation was far removed from the carefully considered efforts of United Nations advisory groups and others to untangle the complex web of nutritional, medical, economic, social, cultural, emotional and other influences which underlie infant feeding practices and their nutritional and health implications.

Largely as a result of publicity and pressure stimulated by a small number of highly vocal groups, the United States Senate Subcommittee on Health and Scientific Research held a hearing in May, 1978, on the marketing of infant formula in less developed countries.*

Following the hearing, the Subcommittee's Chairman met with industry officials and gained agreement with his proposal to request the Director-General of the World Health Organization "to convene a conference of industry representatives, industry critics, nutrition experts and appropriate government officials and health professionals from developing nations... The conference would consider, among other things, a meaningful, uniform code of ethics, acceptable to all infant formula manufacturers."** The suggestion was then made to the World Health Organization that it conduct a meeting to address the overall issue of infant feeding in developing countries, including the marketing of infant formula in those areas. That suggestion was consistent with the World Health Organization's ongoing plans and programs in maternal and child nutrition and in October, 1979,

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* "Marketing and Promotion of Infant Formula in the Developing Nations, 1978" Hearing before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, United States Senate, 95th Congress, 2nd Session, May 23, 1978.

** Letter from Senator E. M. Kennedy dated July 21, 1978.

the World Health Organization and the United Nations Children's Fund jointly held a meeting on Infant and Young Child Feeding. The meeting was attended by about 150 delegates representing industry, consumer interest groups, United Nations Agencies, scientists, and others.

If there were ever any question about the views of the groups who were critical of infant formula marketing, it was clearly answered in a position paper* which one of the more active groups broadly distributed immediately before the October, 1979 WHO/UNICEF Meeting. In presenting its recommendation for a code of marketing for infant formulas, its view was stated simply:

> No firm shall make any expenditure for the purpose of promoting infant formula or other tinned milks for infant use, including but not limited to all forms of communication, donations, or services intended to make persons aware of the availability, characteristics, or uses of such products.

It then said, as if any thread of doubt remained, that:

> The virtue of such a code is that it would simply eliminate all forms of promotion.

It is important to note that a controversial background paper which WHO and UNICEF prepared and issued as <u>the only "official" basis</u> for the 1979 meeting presented <u>their</u> recommendation for the content of a marketing code. It read, in part, as follows:

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*"What We Believe About the WHO/UNICEF Meeting: Plans and Actions," Interfaith Center on Corporate Responsibility, National Council of Churches.

It is recommended that codes of conduct should include at least the following points:

(a) There should be no advertising of breastmilk substitutes to the general public...

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(e) There should be no direct or indirect promotion of breastmilk substitutes through health and health-related services... Posters and other advertising materials should not be displayed in government, nongovernment or private health facilities.

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(g) Sales bonuses or other incentives should not be applied to sales of breastmilk substitutes.

(h) There should be no promotional sales; distribution of free samples to the public should be prohibited; samples supplied to physicians should be strictly for professional examination.

(i) Bottles and teats should not be promoted.*

The joint WHO/UNICEF Meeting developed several recommendations for improving maternal and infant health and nutrition. One of the recommendations was that WHO and UNICEF should arrange for the development of an international code for the marketing of breastmilk substitutes.

Not unexpectedly, WHO's first draft of a code-- issued in early February 1980-- was seriously defective by almost any measure. It contained a long series of unwarranted and absolute prohibitions and restrictions of legitimate commercial activity. In reacting to the WHO's first draft of a code, the United States government said, among other things:

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*"Background Paper Prepared by WHO and UNICEF, Meeting on Infant and Young Child Feeding, Geneva, 9-12 October 1979, FHE/ICF/79.3; pp. 62-63.

> What appeared to be the consensus at the October conference [WHO/UNICEF Meeting, 10/9-12, 1979] was that there should be developed a set of standards for the marketing, distribution, and use of breast-milk substitutes. These might take the form of voluntary guidelines or basic principles, or of model legislation for adoption and adaptation in developing countries where past marketing practices have been deemed harmful. We would, of course, want to engage in negotiations about the content of any such document, but the United States could, in principle, support that approach.
>
> We believe that any document along these lines should be basic, brief and general (avoiding specifics that could make it irrelevant in too many instances), and that it should be sensitive in giving due consideration to the varied health, economic, social, and cultural situations in different countries. But most importantly, any document developed on this issue ought to be one of a guiding or recommending nature. A document with provisions that are mandatory on governments or corporations could not be accepted by the United States.* (emphasis added)

The United States also expressed deep concerns about the process to be followed in developing any statement of principles or "Code." In the same letter, it was stated:

> "The decision to proceed with a 'code' or formal standards should be a deliberate step of the [World Health] Assembly, one that can provide guidance for the approach to be taken. The contents of the document must then be subject to full intergovernmental negotiations."*

*Letter to Dr. Halfdan Mahler, Director General, World Health Organization from Dr. John H. Bryant, Deputy Assistant Secretary for International Health, (then) Dept. of Health, Education and Welfare, March 29, 1980, pp. 1-2.

The second draft of a code of marketing for breastmilk substitutes was released by WHO in April 1980 and was submitted to the May 1980 Thirty-Third World Health Assembly as a progress report* on the code development project. Although the second draft was described by the WHO as "a series of principles," it continued to contain the same kind of unwarranted, unrealistic, and otherwise irrelevant and arbitrary restrictions, prohibitions and requirements which characterized the first draft.

Apparently addressing the United States' concerns about the process WHO had been following in formulating a code, particularly about WHO's lack of any formal authority to formulate such a code, the May 1980 World Health Assembly adopted a resolution** giving WHO the authority to proceed with its code development activity. That resolution, however, failed to accommodate the United States' position that any such code should be developed through a process of "full intergovernmental negotiations." Instead, the resolution left the preparation of the code completely in the hands of the WHO Secretariat with "close consultation with Member States and with all other parties concerned..." The WHA Resolution also directed that WHO should submit its final draft of a code to the World Health Assembly's thirty-member Executive Board for consideration at its sixty-seventh (January 1981) session. The Executive Board would then forward to the Thirty-Fourth (May 1981) World Health Assembly the code with its recommendations including proposals concerning adoption of the code either as a binding regulation in the sense of Articles 21 and 22 of the Constitution of the WHO or as a recommendation in the sense of Article 23.

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* "Thirty-Third World Health Assembly Provisional Agenda, Item 23, Follow-up of WHO/UNICEF Meeting on Infant and Young Child Feeding, Draft International Code of Marketing of Breastmilk Substitutes: Report by the Director General," A 33/6 Add. 1,24 April 1980.

It is noteworthy that during the World Health Assembly's Committee A deliberations on the marketing code, the Assistant Director-General of WHO outlined criteria that WHO would follow in its further drafting of the code. His remarks were generally reasonable but concluded with a disturbing point. From the Provisional Summary Record* of Committee A's discussions, the Assistant Director-General said:

> ...the [WHO and UNICEF] Secretariats would have to do their best in order to ensure that the draft to be presented to the sixty-seventh session of the Executive Board would be comprehensive enough to translate the framework of the October [1979 WHO/UNICEF] meeting; general enough to constitute a useful international instrument common to all countries, flexible enough to provide principles and guidelines for countries with different economic, social and political systems in their efforts to develop their own national legislation in this matter; and effective and clear enough to serve the main purpose on which there was a consensus of all governments and parties concerned, i.e., to emphasize the preservation of breastfeeding, to guarantee that marketing of breastmilk substitutes and weaning foods should be designed not to discourage breastfeeding and to guarantee that there should be no sales promotion, including promotional advertising to the public...

Coupling this last anti-promotion point with the view of the Deputy Executive Director of UNICEF reveals a good deal about the approach WHO was to maintain throughout the code drafting process. In a March 13-14, 1980 consultation with industry representatives, the Deputy Executive Director of UNICEF said that he saw the code as "shoring up any loopholes which were left by the recommendations of the October 9-12, 1979 WHO/UNICEF meeting." The concept of general and flexible principles which could serve as universally valid guidelines was never to be given effect in the drafting of the code.

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*"Extract of Provisional Summary Record of Committee A of WHA 33 on